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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/040,906	01/09/2002	Greta Arnaut	58764.000036	1498

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HUNTON & WILLIAMS LLP  
INTELLECTUAL PROPERTY DEPARTMENT  
1900 K STREET, N.W.  
SUITE 1200  
WASHINGTON, DC 20006-1109

EXAMINER

KUBELIK, ANNE R

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 03/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/040,906	ARNAUT ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Anne R. Kubelik	1638	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 17 January 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 57-58, 63-69, 71, 74, 76-77, 79-81, 83 and 85-86 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 57, 63-69, 74, 79 and 81 is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

1. Claims 57-58, 63-69, 71, 74, 76-77, 79-81, 83 and 85-86 are pending.
2. The advisory action mailed 6 February 2006 was sent in error and is withdrawn.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. The objection to claim 71 is withdrawn in light of Applicant's amendment of the claim.
5. The objections to claims 82 and 84 are withdrawn in light of Applicant's cancellation of the claims.
6. The rejection of claim 77 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention is withdrawn in light of Applicant's amendment of the claim.
7. The rejection of claims 71 and 76 under 35 U.S.C. 103(a) as being unpatentable over Baum et al (US Patent 6,593,293, filed September 1999) in view of Meulewaeter et al (US 6,294,711, filed June 1997), Corbin et al (US 6,489,542, filed November 1998) and Mettler et al (US Patent 6,114,608, filed March 1998) is withdrawn in light of Applicant's amendment of the claims.

### ***Claim Rejections - 35 USC § 102***

8. Claims 83-84 are rejected under 35 U.S.C. 102(e) as being anticipated by Baum et al (US Patent 6,593,293, filed September 1999). The rejection is repeated for the reasons of record as set forth in the Office action mailed 14 July 2005, as applied to claims 71 and 73. Applicant's arguments filed 17 January 2006 have been fully considered but they are not persuasive.

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Baum et al teach a method comprising applying the protein of SEQ ID NO:2 (claims 9-10; column 50, line 25, to column 55, line 15).

Applicant urges that Baum et al does not disclose protecting a plant from *Anticarsia gemmatalis* (response pg 8).

This is not found persuasive because applying the protein of SEQ ID NO:2, as taught in Baum, would inherently be a method of protecting a plant from *A. gemmatalis*.

See, *In re King*, 231 USPQ 136 (CA FC 1986) at pg 138, where it says

Under the principles of inherency, if a structure in the prior art necessarily functions in accordance with the limitations of a process or method claim of an application, the claim is anticipated.

and at pg 138-139, where it says

Contrary to appellant's reasoning, after the PTO establishes a prima facie case of anticipation based on inherency, the burden shifts to appellant to "prove that the subject matter shown to be in the prior art does not possess the characteristic relied on." *In re Swinehart*, 439 F.2d 210, 212-13, 169 USPQ 226, 229 (CCPA 1971). Accord *In re Fitzgerald*, 619 F.2d 67, 70, 205 USPQ 594, 596 (CCPA 1980), quoted with approval in *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985); *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433-34 (CCPA 1977); *In re Ludtke*, 441 F.2d 660, 664, 169 USPQ 563, 566 (1971). Here, appellant's burden before the board was to prove that Donley's structure does not perform the so-called method defined in the claims when placed in ambient light. Appellant did not satisfy that burden. It did not suffice merely to assert that Donley does not inherently achieve enhanced color through interference effects, challenging the PTO to prove the contrary by experiment or otherwise. The PTO is not equipped to perform such tasks. See *In re Brown*, 459 F.2d 531, 535, 173 USPQ 685, 688 (CCPA 1972), quoted with approval in *In re Fitzgerald*; *In re Best*, supra.

Applicant urges that claim 83 is non-obvious (response pg 9).

This is not persuasive, as the rejection is one of anticipation, not obviousness.

### ***Claim Rejections - 35 USC § 103***

9. Claims 58, 77 and 80 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baum et al (US Patent 6,593,293, filed September 1999) in view of Audtho et al (1999, Appl. Environ. Microbiol. 65:4601-4605) and further in view of Schnepf et al (Microbiol. Mol. Biol. Rev. 62:775-806). The rejection is repeated for the reasons of record as set forth in the Office

action mailed 14 July 2005, as applied to claims 71 and 73. Applicant's arguments filed 17 January 2006 have been fully considered but they are not persuasive.

The claims are drawn to a nucleic acid encoding a protein consisting of amino acids 2-49 to 632 of SEQ ID NO:2 or a protein of SEQ ID NO:2, chimeric genes comprising it, plants transformed with it, and a process for using it to render plants insect resistant.

Baum et al teach a nucleic acid, SEQ ID NO:1, which encodes the instant SEQ ID NO:2. Baum et al also teach the expression of the DNA in plants, including corn and cotton, in chimeric gene constructs behind plant promoters, including the CaMV 35S, the FMV 35S, the wound-inducible mannopine synthase, and the SSU promoters, a 5' leader sequence, and with and without chloroplast, vacuolar or secretion transit peptides, and operably linked to a 3' terminator (column 12, lines 30-43; column 23, lines 1-20; column 57, line 50, to column 63, line 22). The plants would inherently be resistant to *Helicoverpa armigera*, *Anticarsia gemmatilis*, *Sesamia nonagrioides*, *S. inferens*, *Chilo suppressalis*, *C. partellus*, *Scirpophaga incertulas*, *S. innotata*, *Cnaphalocrocis medinalis*, *Marasmia patnalis*, *M. exigua*, and *M. ruralis*. Baum et al do not disclose fragments of the nucleic acid encoding a protein consisting of amino acids 2-49 to 632 of SEQ ID NO:2 or of amino acids 1 to 626-631 of SEQ ID NO:2.

Audtho et al teach that another Cry2 protein, Cry2Aa1, is activated by processing at the N-terminal end, with about 49 amino acids being removed from the N-terminus (paragraph spanning the columns, pg 4602, and Table 1).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to modify the nucleic acids taught by Baum et al, to remove about 49 amino acids from the N-terminus of the protein, as described in Audtho et al. One of ordinary skill in the art would have been motivated to do so because truncation of the modified Cry genes results in more

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effective expression in plants (Schnepf et al, pg 793, left column, paragraph 3) and to avoid insect resistance (Schnepf et al, pg 795, left column, paragraph 2).

Applicant urges that the prior art does not provide any motivation to combine the reference teachings because the prior art does not teach or suggest the desirability of Applicant's invention; Audtho discloses Cry2Ae and there is no motivation to combine the disclosures (response pg 9-10).

This is not found persuasive because Schnepf provides the motivation - truncation allows more effective expression in plants and avoids insect resistance (pg 793, left column, paragraph 3, and pg 795, left column, paragraph 2).

Applicant urges that the Office action does not explain why one would be motivated to apply teachings relating to one protein to a different protein with about a 10% sequence difference (response pg 10).

This is not found persuasive. Schnepf indicates that truncation improved expression with several different Cry proteins (pg 793, left column, paragraph 3) and a desire to avoid insect resistance is not limited to only one Cry protein.

Applicant urges that Corbin et al demonstrates that different Cry2A protein types act in different manners when expressed in plants (response pg 10-11).

This is not found persuasive, as Corbin et al is not drawn to truncation but to addition of the TpsuAt transit peptide to a Cry protein.

Applicant urges that Schnepf does not provide motivation to combine, as the cited papers are drawn to Cry1Aa and Cry1Ab proteins that were truncated at their C-terminus (response pg 11).

This is not found persuasive; without the cited papers, Applicant's arguments are only unsupported assertions. The cited papers were not sent. Additionally, Audtho et al teaches that proteolytic activation of the protoxin is an important factor in insect resistance to the toxin (pg 4603, right column, paragraph 2) and that the protein with the 49 amino acid truncation was more toxin than the 63KDa protein (table 1).

Applicant urges that the statement in Schnepf is general and not directed to a specific Cry protein, and that the Cry2A proteins are already the size of a truncated Cry1A protein (response pg 11-12).

This is not found persuasive because the Cry2A proteins are the size of the C-terminal truncated Cry1A proteins, not the N-terminal truncated proteins.

10. Claims 71, 76 and 85-86 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baum et al in view of Audtho et al and further in view of Schnepf et al as applied to claims 58, 77 and 80 are above, and further in view of Meulewaeter et al (US 6,294,711, filed June 1997), Corbin et al (US 6,489,542, filed November 1998) and Mettler et al US Patent 6,114,608, filed March 1998).

The claims are drawn to a chimeric gene construct comprising the CaMV 35S promoter, the Petunia chlorophyll a/b leader sequence, a DNA encoding the TpssuAt transit peptide, a DNA encoding SEQ ID NO:2 and the CaMV 3' termination and polyadenylation region.

The teachings of Baum et al in view of Audtho et al and further in view of Schnepf et al are discussed above. Baum et al in view of Audtho et al and further in view of Schnepf et al do not disclose a chimeric gene construct comprising the Petunia chlorophyll a/b leader sequence.



Meulewaeter et al teach a chimeric gene construct comprising the CaMV 35S promoter, the Petunia chlorophyll a/b leader sequence and a DNA encoding a Cry protein (column 39, lines 49-62).

Corbin et al teach a DNA encoding the TpssuAt transit peptide operably linked in constructs encoding a Cry protein (column 47, lines 11-37).

Mettler et al teach the CaMV 3' termination and polyadenylation region operably linked in constructs encoding a Cry protein (column 8, lines 11-17).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to modify the chimeric gene construct taught by Baum et al in view of Audtho et al and further in view of Schnepf et al, to use the Petunia chlorophyll a/b leader sequence as described in Meulewaeter et al, the TpssuAt transit peptide as described in Corbin et al, and the CaMV 3' termination and polyadenylation region as described in Mettler et al. One of ordinary skill in the art would have been motivated to do so because selection of particular untranslated leader sequence, transit peptide and 3' termination and polyadenylation regions are obvious design choices.

11. Claims 57, 63-69, 74, 79 and 81-82 are free of the prior art, given the failure of the prior art to teach an isolated nucleic acid encoding a protein consisting of amino acids 1 to 626-631 of SEQ ID NO:2.

12. Claims 57, 63-69, 74, 79 and 81 are allowed.



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***Conclusion***

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (571) 272-0801. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg, can be reached at (571) 272-0975.

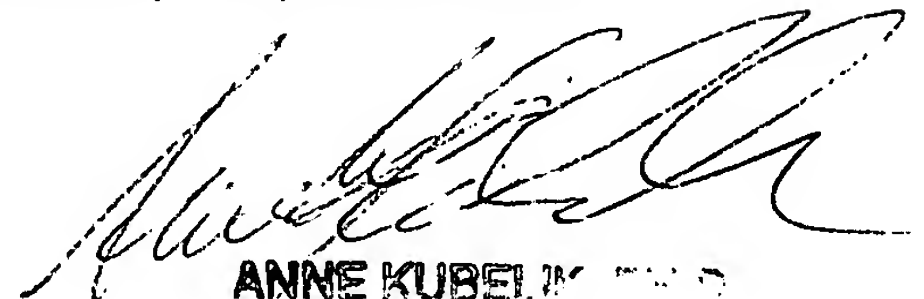
The central fax number for official correspondence is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

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Anne Kubelik, Ph.D.  
March 3, 2006



**ANNE KUBELIK, Ph.D.  
PRIMARY EXAMINER**